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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,781	01/25/2001	Gennady Merkulov	CL001057-CIP	3929

25748 7590 12/31/2002

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EXAMINER
BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	7

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/768,781	Merkulov et al
Examiner	**Art Unit**
Nirmal S. Basi	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 21, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-23* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The Amendment filed 5/21/01 (paper number 5) has not been entered.

2. The Amendment to the figures has not been entered. The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected.

3. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20 and 21 drawn to isolated polypeptide comprising SEQ ID NO:2, classified in class 530, subclass 350.

II. Claims 4-6, 8-11 and 22-23, drawn to isolated DNA, recombinant expression vector comprising said DNA and method of preparing said polypeptide using a cell containing said vector classified in class 536, subclass 23.1, for example .

III. Claims 3, drawn to antibody, classified in class 530, subclass 387.9, for example.

IV. Claims 7, drawn to transgenic non-human animal, classified in class 800, subclass 2, for example.

V. Claims 12, drawn to a method for detecting a polypeptide, classified in class 435, subclass 7.1 for example.

VI. Claim 13 drawn to a method detecting a nucleic acid, classified in class 435, subclass 6.

VII. Claims 14 and 15 drawn to a method for identifying a modulator of a peptide classified in class 435, subclass 7.1.

VIII. Claim 16, drawn to a method of identifying an agent that binds a polypeptide, classified in class 435, subclass 7.1.

IX. Claim 18, drawn to a method of treating a disease or condition mediated by human transporter protein, classified in class 514, subclass 2

X. Claim 19, drawn to a method for identifying a modulator of the expression of the peptide of claim 2, classified in class 435, subclass 7.21

XI. Claim 17, drawn to a pharmaceutical composition comprising identified by the method of claim 16, class and subclass can not be determined because the pharmaceutical composition has not been disclosed.

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

The proteins of Invention I are related to antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

The proteins Inventions I and the methods of Inventions V and VII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention III.

The proteins of Invention I are distinct from the methods of Invention VI wherein the protein of Invention I can neither be used in nor made by the methods of Invention VI.

The methods of Inventions V-X are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

The DNA of Invention II are distinct from the methods of Invention V, and VII-X wherein the protein of Invention I can neither be used in nor made by the methods of V, and VII-X.

The products of Inventions II and the methods of Inventions VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides may be used for the production of proteins.

The products of Invention III are distinct from the method of Invention VI-X wherein the products of Invention III can neither be used in nor made by the method of Invention VI-X.

The products of Inventions III and the methods of Inventions V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used for protein purification by affinity chromatography or used to raise secondary antibodies (ie. Antibodies to self in another animal).

The products of Inventions I-V are distinct because they have distinct functional, chemical and physical properties capable of separate use and manufacture.

The products of Invention IV are distinct from the method of Invention V- X wherein the products of Invention I can neither be used in nor made by the method of Invention V- X.

The products of Invention XI are distinct from the method of Invention VI wherein the products of Invention XI can neither be used in nor made by the method of Invention VI.

The products of Inventions XI and the methods of Inventions V and VII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of claim XI can be used for to produce antibodies.

The products of Inventions I-IV and XI are distinct from each other because they have distinct functional, chemical and physical properties and are capable of separate use and manufacture.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-XI would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

The claims of group I-XI are drawn to a multitude of nucleic acids derived from the (SEQ ID NO:1, 2 and 5), polypeptides (SEQID NO:3 and 4), antibodies thereto and methods which use these transporter compounds. The claims apply to at least two different transporters. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent

and distinct inventions. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under U.S.C.§ 121. Upon election of Groups I-XI, Applicants is additionally required to elect a single nucleic acid, polypeptide, or antibody. This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. The specification is confusing as to the inventions of SEQ ID NOs:1-5. The specification, page 18, third paragraph, discloses Figure 2 provides proteins consisting of the amino acid sequences of SEQ ID NO:2 and 5. Although the sequences in Figure are of a protein, SEQ ID NOs:2 and 5 are nucleic acid sequences. It is also stated the genomic sequence is provided in Figure 3 (SEQ ID NO:3). SEQ ID NO:3 is a polypeptide sequence. Clarification as to the nature and relationship of the sequences disclosed in SEQ ID NOs:1-5 is required because it is not clear how the sequences are related.

An election to prosecute one of the groups listed I -XI must be made. Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
December 28, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600